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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,757	06/25/2001	John E. Ahern	B0410/7282D1	2885
23628 7590 10/16/2008 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				
EXAMINER				
STIGELL, THEODORE J				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
10/16/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/888,757

Applicant(s)

AHERN ET AL.

Examiner

THEODORE J. STIGELL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date: _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Objections

The objection to claim 30 is withdrawn in light of the claim amendments submitted on 7/9/2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-26 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Murphy-Chutorian (5,925,012). Murphy discloses an apparatus (see at least Figures 4 and 5) capable of delivering and sequentially implanting one or more of a plurality of pellets (210) within the myocardial tissue comprising an elongate flexible catheter body (106) having a length and a flexibility sufficient to allow for transluminal delivery, a delivery chamber (106) coupled to the distal end of the catheter body and having space for carrying pellets and a port (118) for releasing the pellets, an actuator (212, 102, 220) coupled to the delivery chamber and capable of delivering the pellets through the port, the distal tip (117) of the chamber being sharp, further comprising a control mechanism coupled to the actuator (see column 17, line 45- column 18, line 10

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for a disclosure of multiple control mechanisms), further including a steering mechanism (proximal end of the device) that could be used to turn the distal end of the device, wherein the delivery channel can hold multiple pellets of therapeutic agent, wherein the actuator includes a plunger (220), further including a port within the chamber formed from a plurality of flexible fingers (114), and wherein the delivery chamber has arcuate shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy-Chutorian (5,925,012) in view of Dragan (USPN 4,457,712). Murphy-Chutorian meets the claim limitations with respect to claim 20 above but fails to include the ratchet assembly of claim 27 and the threaded plunger of claim 28. Murphy does

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contemplate using multiple actuator configurations (see column 17, line 45- column 18, line 10).

However, Dragan discloses an injection device that includes both the teaching of a plunger with ratchets and threads. See figures 6 and 17.

At the time of the invention, it would have been obvious by one skilled in the art to substitute the actuator of Murphy for the ratchet and threads as taught by Dragan. One skilled in the art would recognize that both threads and ratchets are designed to move the plunger from one end to another in order to dispense a material. The motivation for the substitution would have been in order to enhance the control of the movement of the plunger for dispensing the material.

Response to Arguments

Applicant's arguments filed 4/21/2008 have been fully considered but they are not persuasive.

In response to the applicant's argument that Murphy-Chutorian does not disclose a flexible catheter, the examiner respectfully disagrees. The examiner notes that "flexible" is an extremely broad and relative term and can apply to almost any material. The examiner gives the example of steel which is known to be a rigid material but inherently also has a certain amount of flexibility. The examiner also contends that further limiting "flexible" with the limitation of "flexibility sufficient to allow for transluminal delivery through a patient's vasculature to a target region of the myocardium" is not sufficient to distinguish over Murphy-Chutorian. The examiner is interpreting this

limitation to be functional of which Murphy-Chutorian is capable of meeting. A user can insert the device of Murphy-Chutorian inside a blood vessel that is directly adjacent to the heart. The device would then meet the limitations of "long enough" and "flexible enough" to reach the myocardium. The examiner also notes that the device of Murphy-Chutorian does not have to specifically disclose the limitations discussed above, but only be capable of performing them. The examiner maintains these responses for the arguments presented for claim 23 as well.

In response to the applicant's argument that Murphy-Chutorian does not disclose a steering mechanism, the examiner respectfully disagrees. The examiner maintains that a user can provide a small degree of steering to the distal end by moving the proximal end (defined as the steering mechanism) of the device.

In response to the applicant's argument that Murphy-Chutorian does not disclose a port formed from a plurality of converging fingers, the examiner respectfully disagrees. The examiner contends that the tapered element (114) can serve as a port formed from a plurality of converging fingers. The examiner contends that a portion of a tube (portion 114) can be interpreted as an integral plurality of flexible fingers. Furthermore, it is not clear where the applicant's device is disclosed as having two ports (one port claimed in 20 and one port claimed in 32).

In response to the applicant's argument that it is not obvious to combine the teachings of Murphy-Chutorian and Dragan, the examiner respectfully disagrees. The examiner contends that the devices are analogous in that they are both devices

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adapted for delivering material to the inside of the body and therefore a combination is proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763